REMARKS/ARGUMENTS

Claims13-16, 18-22, 25-27, 29-31, 34, and 36-46 remain in this application. Claims 1-4, 17, 23, 24, 28, 32, 33, and 35 have been cancelled without prejudice. Applicants reserve the right to pursue such cancelled subject matter in subsequent continuation applications. Claim 26 has been amended to recite "a first potion of particles." Support for such amendment can be found throughout the specification, such as page 17, lines 13-16. New claims 36-46 have been added. Support for such claims can be found throughout the specification and original claims, e.g., original claims 13, 14, 15, 19, and 25. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Rejection Under 35 USC 102

Claims 1-3, 13-19, 21, 23, 24, and 29 were rejected under 35 USC 102 as being anticipated by US Patent No. 5,885,616 (the '616 Patent). See Pages 2-3 of the Office Action. According to the Office Action, "the '616 Patent teaches a dosage form comprising an immediate release drug portion and a controlled release drug portion (abstract)." See Page 2 of the Office Action.

Applicants respectfully disagree, but in the interests of furthering this application to allowance, as discussed above, independent claim 1 (from which claims 2-3, 13-19, 21, 23, 24, and 29 originally depended) has been cancelled without prejudice. Claims 2-3, 13-19, 21, 23, 24, and 29 have either been similarly cancelled or amended to now depend from independent claim 26, which claim was not rejected above.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 USC 103

Claims 1-4 and 13-35 were rejected under 35 USC 103(a) as being unpatentable over US Patent No. 6,126,969 (the '969 Patent) in view of US Patent No. 5,885,616 (the '616 Patent). See Pages 3-5 of the Office Action. According to the Office Action,

> "The '969 Patent teaches a dosage form comprising an immediate release drug portion and a controlled release drug portion (abstract). . . . The reference is silent to the ratio of the instant claims. As discussed above the '616 Patent discloses an immediate and a

> sustained release formulation comprising a sustained release coating comprising an insoluble polymer and an enteric polymer comprising a sustained release coating comprising an insoluble polymer and an enteric polymer in a ratio from 1:4 to 4:1 within the limits of the instant claims (col. 8, lin. 28-34). The artisan of ordinary skill would be motivated to use the coating composition of the '616 patent in order [to] provide improved sustained release of the active agent."

See Pages 4-5 of the Office Action. Applicants respectfully disagree.

Claim 26 now recites the following:

> A liquid suspension dosage form comprising:
> a) a first portion of particles containing an NSAID and/or acetaminophen, said NSAID and/or acetaminophen being released from the dosage form in a substantially immediate manner upon contact of the dosage form with a dissolution medium;
> b) a second portion of particles containing NSAID and/or acetaminophen, said NSAID and/or acetaminophen being released from the particles in a controlled manner upon contact of the dosage form with the dissolution medium; and
> c) water, or mixtures of water and a pharmaceutically acceptable water-miscible co-solvent selected from the group consisting of glycols, alcohols, and glycerol,
> wherein said particles in said second portion are comprised of a core that is substantially covered by a coating thereon, and said coating is comprised of a controlled release composition comprising an enteric polymer and an insoluble film forming polymer wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1, said first portion of particles and said second portion of particles are suspended in component c), and the dosage form has a duration of therapeutic effect for at least about 12 hours after administration. (emphasis added)

Such a liquid suspension dosage form is not taught, not suggested, by the '616 Patent or the '969 Patent, alone or in combination.

With respect to the '969 Patent, it fails to disclose, or suggest, a liquid suspension in which such two types of particles are suspended. Second, the particles disclosed in the '969 Patent do not contain a coating that is comprised of a controlled release composition comprising both an enteric polymer and an insoluble film forming polymer. In fact, the '969 Patent does not disclose a particle containing any enteric polymer. Rather, the'969 Patent actually teaches away from the use of such polymers. For example, the '969 Patent states that it desires a "predictable rate which is independent of inter-and intra-subject physiological variations such as pH. . . . The resulting combined immediate-release/sustained-release formulation provides higher reproducibility of drug release rates than other sustained-release dosage forms utilizing conventional enteric sustained-release coating compositions . . . ." See, e.g., col. 5, lines 45-60 of the '969 Patent.

Applicants further wish to address the assertion in the Office Action that "the '616 Patent discloses an immediate and a sustained release formulation comprising a sustained release coating comprising an insoluble polymer and an enteric polymer comprising a sustained release coating comprising an insoluble polymer and an enteric polymer in a ratio from 1:4 to 4:1 within the limits of the instant claims (col. 8, lin. 28-34)." See Page 4-5 of the Office Action. Applicants again respectfully disagree and wish to note that the ratios on col. 8, lines 28-34 of '616 Patent referenced in the Office Action are not the ratio of the insoluble polymer and an enteric polymer. Rather, these are the weight ratios of the active ingredient (diltiazem) in the two drug compartments in the particle.

Therefore, even if an artisan of ordinary skill would be motivated to combine the teachings of the '969 Patent and the '616 patent (which the Applicants do not assert), such combination would not result in the dosage form of independent claims 26 or 31.

The Office Action further asserts on page 5 that:

> "With these aspects in mind it would have been obvious to combine the sustained release coated particles of the '616 patent into the liquid suspension of the '969 Patent. It would have been obvious to combine the particles into the suspension of the '969 [Patent] with an expected result of a controlled release liquid suspension with improved release over a 24 hour period."

Applicants again respectfully disagree.

As discussed above, while the '969 Patent does disclose particles containing enteric polymers, it does not disclose the particles recited in the pending claims. Further, as also discussed above, the '616 Patent teaches away from the use of particles containing enteric polymers. Thus, Applicants assert that one of ordinary skill in the art would certainly not combine the enteric polymer containing particles of the '969 Patent with the teachings of the '616 Patent, which teaches away from using such particles.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance.

Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5015/WEM.

Respectfully submitted,

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